

## Patient Medication Information

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTEPEZZA®

#### teprotumumab for injection

#### Lyophilized powder for concentrate for solution for intravenous infusion

This patient medication information is written for the person who will be taking **Tepezza**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about Tepezza, talk to your healthcare professional.

### Serious Warnings and Precautions

#### Diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic state (HHS)

Diabetic ketoacidosis and hyperosmolar hyperglycemic state, both serious potentially life-threatening complications of high blood sugar and diabetes, have been reported in patients treated with Tepezza.

- Before starting Tepezza, tell your healthcare professional if you know that you are at risk for diabetes (have high blood sugar, glycosylated hemoglobin or hemoglobin A1c) or have diabetes.
- Know the symptoms of DKA and HHS and contact your healthcare provider and get medical care immediately if they occur:
  - Increased thirst and increased need to urinate
  - Dark yellow or brown urine
  - Nausea and vomiting
  - Abdominal pain
  - Feeling more tired than normal, difficulty thinking clearly
  - Fruity smelling breath
  - Weight loss
  - Loss of consciousness

#### **What Tepezza is used for:**

- Tepezza is used to treat adults with moderate or severe active Thyroid Eye Disease (TED).

#### **How Tepezza works:**

Tepezza is a medicine that contains the active substance teprotumumab, which is a humanized monoclonal antibody and attaches to specific proteins called type 1 insulin-like growth factor receptor (IGF-1R) in your body. When teprotumumab binds to IGF-1R, it blocks its activation and signaling.

**The ingredients in Tepezza are:**

Medicinal ingredient(s): Teprotumumab

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 20, and trehalose dihydrate

**Tepezza comes in the following dosage form(s):**

Tepezza 500 mg / single-dose vial for intravenous infusion.

**Do not use Tepezza if:**

- you are allergic or sensitive to teprotumumab or to any of the ingredients in Tepezza (see “What are the ingredients in Tepezza”).
- you are pregnant or plan to become pregnant.

If you are not sure, talk to your healthcare professional before being given Tepezza.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Tepezza. Talk about any health conditions or problems you may have, including if you:**

- Have hearing loss or impairment
- Have high blood sugar or diabetes
- Have inflammatory bowel disease (IBD)
- Are pregnant or plan on becoming pregnant
- Are breastfeeding or plan on breastfeeding

**Other warnings you should know about:****Allergic reactions**

Tepezza can cause infusion reactions. Tell your healthcare professional if you get any of these symptoms during or after your infusion: difficulty breathing, chest pain, fast heartbeat, dizziness, loss of consciousness, redness, flushing of the skin or a rash, chills and/or shivering, feeling sick or swelling of your face, tongue or throat.

**Hearing loss and other hearing related problems**

Tepezza may cause severe hearing loss which in some cases may be permanent. Symptoms of hearing problems are listed below under Serious side effects and what to do about them. Contact your healthcare professional if you notice any changes in your hearing at any time. Your healthcare professional will test your hearing before starting Tepezza, during treatment and after completing the treatment.

During treatment with Tepezza, avoid other risks for hearing problems if possible, including smoking, loud sounds and taking other medications that can affect your hearing.

## Hyperglycemia

Increased blood sugar (also known as increased blood glucose and hyperglycemia) may occur during treatment with Tepezza, especially if you have diabetes or are at risk for diabetes before starting treatment. Your healthcare professional will test your blood sugar and other markers of diabetes before starting Tepezza, at regular intervals during the period you are receiving Tepezza and for at least 6 months after stopping Tepezza.

If your blood sugar or other diabetes-related tests are abnormal, your healthcare professional will discuss treatment options with you. You may need to temporarily stop Tepezza until your blood sugar return to normal.

Some people treated with Tepezza have experienced severe, potentially life-threatening complications associated with high blood sugar. See Serious Warnings and Precautions Box at the beginning of this leaflet.

## Inflammatory bowel disease

If you have inflammatory bowel disease (Crohn disease, ulcerative colitis or another type of colitis), Tepezza may cause a relapse of your disease.

## Pregnancy

Tell your healthcare professional if you are pregnant, think you might be pregnant or are planning to become pregnant. **You must not use this medicine if you are pregnant because it may harm your unborn baby.**

Women who are able to get pregnant should use an effective form of birth control prior to starting treatment, during treatment and for at least 6 months after the final dose of Tepezza. **If you become pregnant during treatment, tell your healthcare professional immediately and stop taking Tepezza.**

## Breast-feeding

Tepezza should not be used during breastfeeding because it is not known if Tepezza passes into your breast milk and if this could harm your baby.

## Driving and operating machinery

While you are being treated with Tepezza you may be more tired than normal or have headaches. This may impair your ability to drive or use machines. Do not drive or operate machines if you have these symptoms.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

## How to take Tepezza:

- Tepezza will be given to you by a qualified healthcare professional.
- Tepezza is given through a needle placed in a vein (IV or intravenous infusion) in your arm.
- Before treatment with Tepezza, your healthcare professional will complete specific screening tests including blood glucose and hearing assessments.
- Women who are able to get pregnant: your healthcare professional will do a pregnancy test before starting Tepezza. Pregnancy must be excluded before you start Tepezza.

**Usual dose:**

The dose of Tepezza depends on your body weight. The recommended dose is 10 mg per kilogram of your body weight for the first dose. You will receive a further 7 infusions every three weeks at a recommended dose of 20 mg per kilogram of body weight.

The first 2 infusions will usually last about 90 minutes. If these first 2 infusions are well-tolerated, further infusions may be given to you over a period of 60 minutes. If not well tolerated, the minimum time for subsequent infusions will remain at 90 minutes.

**Overdose:**

If an overdose happens, your healthcare professional will monitor you for any signs or symptoms of side effects and treat these symptoms if necessary.

If you think you, or a person you are caring for, have taken too much Tepezza, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no symptoms.

**Missed dose:**

If you miss an infusion, your healthcare professional will decide when you should be given your next dose of Tepezza. You should discuss this with your healthcare professional.

**Possible side effects from using Tepezza:**

These are not all the possible side effects you may have when taking Tepezza. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Change in the sense of taste
- Dry skin
- Ear discomfort (ear pressure, ear fullness feeling of clogged/plugged ears)
- Feeling tired
- Headache
- Menstrual disorders (missing period(s), spotting, and painful menstruation or cramps)
- Nausea
- Change in body weight

Serious side effects and what to do about them			
Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
<b>High blood sugar</b> (hyperglycemia)		X	
<b>Hearing impairment</b> (deafness, a disorder in loudness perception, an impaired ability to hear certain sounds, echoing of the voice in the ears, ringing in the ears)		X	X
<b>Muscle spasms</b> (involuntary muscle contractions)		X	
Hair loss		X	
Diarrhea		X	
<b>COMMON</b>			
<b>Infusion-related reactions</b> (e.g., headache, fast heartbeat, difficulty breathing, redness of the face/feeling hot, muscle pain)		X	X
<b>UNCOMMON</b>			
<b>Diabetic ketoacidosis</b> (increased thirst, increased urination, nausea, vomiting, abdominal pain, feeling tired, difficulty thinking clearly/groggy, fruity smelling breath, weight loss)		X	X
<b>Inflammatory bowel disease</b> (relapse of IBD disease)		X	X
<b>RARE</b>			
<b>Hyperosmolar hyperglycaemic state</b> (increased thirst, increased urination, dark brown or yellow urine, weight loss, feeling tired/groggy, loss of consciousness)		X	X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## Storage:

Refrigerate at 2°C to 8°C in original carton.

Protect from light. **Do not freeze.**

Keep out of reach and sight of children.

The product does not contain any preservative. The combined storage time of reconstituted Tepezza solution in the vial and the diluted solution in the infusion bag containing 0.9% Sodium Chloride Injection is a total of 4 hours at room temperature 20°C to 25°C or up to 48 hours under refrigerated conditions 2°C to 8°C protected from light. If refrigerated prior to administration, allow the diluted solution to reach room temperature prior to infusion.

## If you want more information about Tepezza:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.amgen.ca>, or by calling 1-866-502-6436

This leaflet was prepared by Amgen Canada Inc.

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